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2. Patent application number (The Patent Office will fill in this part)	0308607.1		14 APR 2003
3. Full name, address and postcode of the or of each applicant (underline all surnames)	WATTS, Robert John Venards Cottage North Gorley Fordingbridge Hampshire SP6 2PJ United Kingdom Patents ADP number (if you know it) If the applicant is a corporate body, give the country/state of its incorporation		
	730451 2001		
4. Title of the invention	Ankle-Foot Orthosis		
5. Name of your agent (if you have one)	RGC Jenkins & Co.		
"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)	26 Caxton Street London SW1H 0RJ United Kingdom		
Patents ADP number (if you know it)	03966736001		
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Signature

Date 14 April, 2003

R.G.C. Jenkins & Co.

R.G.C. JENKINS & CO

12. Name and daytime telephone number of person to contact in the United Kingdom

Mark Milhench 020-7931-7141

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ANKLE-FOOT ORTHOSIS

FIELD OF THE INVENTION

This invention relates to ankle-foot orthoses.

5

BACKGROUND TO THE INVENTION

Orthoses are mechanical devices which impose forces upon a limb of a patient and which can be used for a variety of different purposes. For example, orthoses can be provided for supportive, functional, corrective or protective purposes, or indeed for a combination of these.

10

Ankle-foot orthoses are typically used to provide protection to the ankle and foot of a patient as well as to provide support against excessive plantarflexion, or "foot-drop" as it is more colloquially known. Foot plantarflexion is a medical condition that results from disease or congenital abnormality. Patients affected by the condition typically experience difficulty in walking as their feet tend to drop when lifted off the ground, and to avoid stumbling they typically have to lift their foot higher than they would otherwise have to. It is also not atypical for patients to have problems during the push-off phase of their gait, as a typical sufferer will tend also to exhibit poor, or impaired, dorsiflexion.

15

20

The primary function of an ankle-foot orthosis is to provide a resistance to plantarflexion which helps keep the patient's foot in the correct position when the foot is lifted off the ground. As well as this resistive function, a good ankle-foot orthosis should also provide a degree of assistance to dorsiflexion during the push-off phase of a patient's gait.

25

A variety of different ankle-foot orthoses have previously been proposed for resisting plantarflexion, and in some cases for additionally assisting dorsiflexion.

30

Figs. 1 and 2 are schematic representations of what is commonly known in the art as an "under foot" orthosis 10. As this colloquial name suggests, the orthosis fits under the foot, and in this case outside of a shoe 12. This particular device cannot be worn without a shoe, and as such the shoe is

an integral component of the orthosis. The orthosis comprises a pair of supporting metal rods 14, one connected to either side of the shoe 12 in the region of the heel 16. The rods are each connected to the shoe by means of a plantarflexion stop 18 that resists foot drop, and springs (not shown) may be provided to assist dorsiflexion. The upper ends of the rods are connected to a supporting band which is adapted to be secured about the calf of a patient. From Fig. 2 it can be seen that the supporting strap functions to secure the orthosis about the patient's calf, and the plantarflexion stops 18 and shoe 12 provide support under the patient's foot to resist plantarflexion.

Figs. 3 and 4 illustrate another previously proposed "under foot" orthosis which must also be used with a shoe that provides close contact between the shoe and the foot in the region of the instep. In this example, the orthosis 22 comprises a one-piece plastics moulding 23 which comprises a calf abutting region 26 and a sole abutting region 28. The top of the calf abutting region 26 is provided with a closure mechanism 27 that enables the device to be secured to the calf of a patient. The sole abutting region 28 acts in conjunction with the shoe 30 to support the foot of the patient. The stiffness of the plastics moulding and the shape thereof in the region of the ankle defines the amount of resistance to plantarflexion. If more resistance is required, then the gap across the front of the ankle can be reduced, or the stiffness of the plastics material can be increased.

Fig. 5 is a functional equivalent to the orthosis of Figs. 3 and 4, and as such is similar in many respects to the orthosis shown in Figs. 3 and 4. The chief difference is that the device shown in Fig. 5 is an "over foot" orthosis, meaning that the orthosis fits over the front (dorsal) aspect of the foot, rather than under it as in the device of Figs. 1 to 4. As shown the device comprises a plastics shell 32 which is worn up against the shin, and which is secured around the calf by means of an appropriate securing band 34. The orthosis includes a stirrup 36 which fits over the foot in the region of the instep, and it is the stirrup which provides the patient with a resistance to plantarflexion.

All of the aforementioned orthoses are sufficient to provide a patient with a device which is operable to resist plantarflexion. However, it is also the case that each of them has a number of attendant disadvantages.

5 A first disadvantage is that all of the aforementioned devices are extremely large and bulky bits of equipment which are clearly visible when worn. This means that a patient wearing one of these devices is immediately singled out as being "abnormal", and this can have a particularly adverse effect on a patient's state of mind.

10 A further disadvantage is that all of these devices must be worn with shoes, and those shoes may have to have been specially manufactured either to include the appropriate plantarflexion stops (and optional springs), or simply to be large enough in the right places to accommodate an in-shoe medical device. As it is difficult (if not impossible) for a patient to use these devices with normal "off-the-shelf" footwear, the overall cost of the orthosis
15 (including ongoing costs) is typically greatly increased. It also means that a patient who wishes to undertake some activity without shoes, such as swimming for example, would have to undertake that activity without having been provided with any means for resisting plantarflexion.

20 Another financial disadvantage of these devices is associated with the fact that they each need to be tailored for a particular patient, and fitted by a competent professional. For example, the devices shown in Figs. 3 to 5 all must be closely moulded by a technician to the shape of the patient's foot and leg, and the fitting process will most likely have to be repeated each time the patient acquires a new pair of shoes.

25 Another disadvantage associated particularly with the orthoses shown in Figs. 3 to 5 is that they can be very uncomfortable to wear as the weight of the patient is always bearing down onto a rigid plastics shell. It is not uncommon for the shell to dig into the sole of the patient's foot and cause quite considerable discomfort.

30 Yet another attendant disadvantage associated particularly with the orthoses shown in Figs. 3 to 5 is that they typically provide very little

assistance to dorsiflexion of the patient's foot. Typically, the plastics materials used are such that they are relatively difficult to flex and bend, and this means that they are not good at storing energy which can be released to assist dorsiflexion during the push-off phase of a patient's gait.

5 Another previously proposed orthosis, which avoids some of the
aforementioned problems, is described in US Patent No. 4,559,934. This
orthosis is composed of four discrete components, namely an elastic support
stocking, a dorsal plate which is anatomically fitted to the dorsum of the foot,
an elastic connector which is connected to the bottom end of the plate, and a
10 retaining fitting to which the elastic connector is attached in use. The elastic
stocking comprises a standard elastic support stocking such as may be
purchased in any pharmacy or chemist, and the plate is attached to the
stocking by means of a pair of pockets which are sewed onto the sock. Once
the plate has been fitted into the pockets, the elastic connector is drawn
15 through a slit in the plate, and adhered – for example by means of a
mechanical hook and loop fastener – to the retaining fitting. By selecting an
appropriate tension for the elastic, the foot of the patient can be raised to the
required degree.

 This device is significantly more inconspicuous and comfortable than
20 the devices shown in Figures 1 to 5. However, it still is reasonably
noticeable, particularly when the foot is viewed side-on. The reason for this is
that the portion of the elastic connector fed through the slit is spaced from the
body of the sock when connected to the retaining fitting 11, and this tends to
make the ankle of the patient appear significantly wider than it otherwise
25 would have been.

 It is also the case that it is typically quite difficult for a patient to put
the device on and take the device off (due to the number of separate
components), and it is very easy for the patient to inadvertently select an
insufficient or excessive resistance to plantarflexion simply by pulling too
30 little or too much of the elastic through the slit. This last disadvantage is
exacerbated by the fact that it is difficult for the patient to adjust the resistance

to plantarflexion when their foot is off the ground, and as a consequence it is not uncommon for a patient wearing such a device to take several attempts to adjust it correctly.

To alleviate the problems set out above, we have previously provided
5 (see granted UK Patent No. 2330309) a sock-like structure which is formed of a resiliently flexible material – such as silicone for example. The sock-like structure, by virtue of its resilience, provides a resistance to plantarflexion and the inherent resilience of the material allows it to store energy which can be released to assist dorsiflexion. The orthosis can be coloured to mimic the
10 colour of the patient's skin (and as such it is cosmetically pleasing), can comfortably be worn in a normal off-the-shelf shoe, and need not be worn with a shoe in order to provide a beneficial effect.

This orthosis provides a quantum leap in the field, and alleviates most of the disadvantages set out above. However, it does still suffer from the
15 disadvantage that it must be carefully fitted by a clinical technician. This means that it can take a considerable amount of time to make and fit the orthosis, and the most immediate drawback of this is that our previously proposed device is still relatively expensive.

It is an aim of the present invention to provide an orthosis which
20 avoids, or at least alleviates, the problems set out above. In particular, it is an aim of the invention to provide an orthosis which functions comparably well to that which we previously proposed, whilst being significantly less expensive to produce.

STATEMENT OF INVENTION

25 In pursuit of the above mentioned aims, a preferred embodiment of the invention provides an ankle-foot orthosis that comprises: an elastic (sock-like) structure formed of contiguous first and second tubular members, said second tubular member being set at an angle to the first tubular member to define, at least in use, a generally L-shaped cavity configured to accept and fit closely
30 about the foot and ankle of a patient; and a rib which is permanently bonded or otherwise permanently affixed to a region of the structure which overlies

the dorsum of the patient's foot in use, said rib being formed of a flexible material that has a resilience appropriate for resisting the particular degree of plantarflexion experienced by the patient.

5 The principal advantage of this orthosis, over that which we previously proposed, is that it is significantly less expensive to manufacture. For this reason, our new orthosis is well suited for commercial retail purposes, for example in chemists or pharmacies, where patients can purchase suitable devices with the minimum of professional assistance. Further advantages of our orthosis (as compared to other previously proposed devices) are: (a) it can
10 be put on and taken off quickly, (b) it is highly inconspicuous, (c) it does not need adjusting, (d) it does not need to be worn with a shoe, and (e) it is significantly more comfortable than some previously proposed devices.

In a highly preferred embodiment, the elastic structure comprises a compression stocking operable to exert a compressive force of more or less
15 than at least 5 mm Hg (approximately 670 Pascals) on the foot and ankle of the patient.

In another highly preferred embodiment, the rib is of silicone elastomer. The resilience of the rib may be varied by, for example, varying the thickness of the rib. Alternatively, or additionally, the resilience of the rib
20 may be varied by varying the composition of the elastomer. The rib could be, for example, of 35 shore silicone elastomer.

Further objects, features and advantages of embodiments of the invention will be apparent from the description which follows:

BRIEF DESCRIPTION OF THE DRAWINGS

25 Various preferred embodiments of the invention will now be described, by way of illustrative example only, with reference to the accompanying drawings, in which:

Figs. 1 and 2 are schematic representations of a previously proposed under-foot orthosis;

30 Figs 3 and 4 are schematic representations of another previously proposed under-foot orthosis;

Fig. 5 is a schematic representation of a previously proposed over-foot orthosis;

Figs. 6a and 6b are schematic representations of an orthosis in accordance with an embodiment of the invention; and

5 Figs. 7a to 7e are schematic representations of an orthosis in accordance with another embodiment of the invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Fig. 6a is a perspective view of an embodiment of the invention. The orthosis depicted in Fig. 6a is shown as it would appear when worn by a patient (the patient's foot and ankle having been omitted for clarity). When not being worn by the patient, the orthosis assumes a more two-dimensional shape to facilitate storage.

As shown, the orthosis comprises an elastic generally sock-like structure 50. The sock is comprised of a first tubular portion 52, and a contiguous second tubular portion 54 which in most instances will have been integrally formed with the first tubular portion.

The first and second tubular portions are set at an angle to one another to provide, at least in use, a generally L-shaped internal cavity 56 which is sized to accept and fit closely about the foot and ankle of a patient (not shown).

A resiliently flexible rib 58 is provided on the structure, and extends from a proximal edge 60 of the orthosis (which locates on or slightly above the ankle of the patient when worn) to a distal edge 62 of the orthosis (which locates in the region of the metatarsal heads when worn by the patient) along the dorsum of the patient's foot. The rib is formed to have a curved cross-sectional shape (i.e. to be concave when viewed from the cavity 56), and the rib's radius of curvature is chosen to be less than the radius of curvature of a typical foot.

When the orthosis is worn by a patient, the patient's foot and lower leg bias the rib (against its natural resilience) to increase its radius of curvature so that it matches that of the patient's foot and lower. Increasing the rib's radius

of curvature causes the rib, by virtue of its inherent resilience, to exert a compressive force on the dorsum of the patient's foot and this force allows the rib to firmly grip the patient's foot.

5 As mentioned above, the rib of this embodiment is permanently attached to the structure during the orthosis' manufacture. The resilience of the rib can be tailored to provide a resilience that is appropriate for resisting the particular degree of plantarflexion experienced by the patient.

10 In an alternative arrangement that is particularly well suited for mass-production, manufactured orthoses may be provided with a resilience that falls within one of a number of discrete ranges - for example a low resilience, a medium resilience and a high resilience. Any given patient then need only select an orthosis with a resilience that is appropriate for the particular degree of plantarflexion that they experience.

15 In a highly preferred embodiment, the rib 58 is formed of silicone elastomer directly onto the structure 50. It is conceivable that other materials could be used, such as rubber, polypropylene or plastics - but the highly resilient nature of silicone coupled with its ease of use means that it is necessarily the most preferred material.

20 The rib may be formed on the structure in any of a number of different ways that will be apparent to persons skilled in the art. By way of illustrative example a so-called milling process more suited for the manual production of a silicone rib will now be described. Methods more appropriate for mass-production are currently being developed. As an alternative to forming the rib on the structure, it could of course be formed separately and then permanently
25 affixed to the structure by means of an adhesive or any other suitable mechanism.

In this illustrative example, the silicone could be one of two suitable elastomers, HCR9960 and MED4035, both of which are sold by Nusil Technology of 1050 Cindy Lane, Carpinteria, California, USA. HCR9960
30 has a working time of approximately 12 hours, whereas MED4035 has a shorter working time of roughly 3 to 4 hours, after which the elastomer cures.

The elastomers are thermosetting, and are preferably strained through a 200 mesh screen to remove particulate contaminants before the rib is formed.

Both of these elastomers are supplied as A and B components, which are then subsequently combined on a rolling mill, or other suitable device, prior to use. In this example, equal measures of A and B components are used and the B component is first softened on the rolling mill following which the A component is then softened on the mill. An equal weight of component B is then added to component A, and the two components are then thoroughly mixed. At this stage it is recommended to keep the temperature of the material as low as possible so as to maximise the table life of the elastomer.

Once thoroughly mixed, the elastomer may then be built up in layers on a sock-like structure 50 which has been stretched over an approximately foot-shaped anvil. The elastomer is then left for 3 to 4 hours to cure - although this may be accelerated by heat. Once the elastomer has cured the structure 50 can be removed from the anvil, whereupon the natural resilience of the elastomer causes the rib to curl inwards to increase its radius of curvature - the resulting advantage of this having previously been described herein.

The resilience of the rib may be varied as required to provide a appropriate for alleviating the particular severity of the condition experienced by the patient. This variance in resilience may be provided, for example, by varying the thickness of the rib. Alternatively, or additionally, the resilience of the rib may be varied by varying the composition of the elastomer. As an illustrative example, the rib could be of 35 shore silicone elastomer.

The sock-like structure 50 of this embodiment is, as has been mentioned above, of an elastic material, and in a highly preferred embodiment is sufficiently elastic to exert a compressive force on the foot and ankle of the patient. That force may be more or less than at least 5 mm Hg (roughly 670 Pascals).

In general terms the sock-like structure may be a so-called compression stocking, and a distinction should be drawn between this type of

elastic stocking and a commonly available support stocking of the type that may be purchased in any chemist or pharmacy. Support stockings sold under the trade name Tubigrip[®] are one example of a commonly available support stocking, and this Tubigrip[®] stocking exerts much less of a compressive force on the foot and ankle of the wearer than a compression stocking of the type referred to herein.

Whilst it would of course be possible to form a silicone rib on one of these typical support stockings, it is likely that the stocking would provide insufficient elastic force to keep the rib in close abutment with the lower leg of the patient whilst walking. In particular, it is likely that the weight of a foot (and shoe) lifted off the ground would simply cause the proximal end of the stocking to elastically overextend with the result that the rib would then no longer be in abutment with the lower leg, and the foot would be allowed to drop.

In contrast, compression stockings of the ilk referred to herein exhibit an elastic force which is sufficient to keep the rib in close abutment with the lower leg of the patient when the patient's foot is off the ground. This is important because at this point in the patient's gait it is, of course, only the close-coupling of the rib to the leg provided by the elastic stocking which keeps the patient's foot in the correct position.

As with the resilience of the rib, the compressive force provided by the sock-like structure may be varied to, for example, help treat other conditions such as the effects and symptoms of venous insufficiency, for example varicose veins. It is also conceivable for different regions of the sock-like structure to provide different compressive forces. For example, the sock-like structure may exert a greater compressive force on the foot of the patient than on the ankle in order to provide a pumping effect to assist blood flow to and from the foot.

Fig. 6b is a front view of the orthosis shown in Fig. 6a illustrating the manner in which the rib 58 extends from the proximal edge 60 of the sock-

like structure 50 of the orthosis down the dorsum of the foot to the distal edge 62 of the structure 50.

Fig. 7a is a perspective view of another embodiment of the invention. The orthosis of this embodiment is similar in a number of respects to that of the previous embodiment in that it comprises a generally sock-like structure 70 on which a rib 71 has been formed or otherwise provided. For brevity, features common between the two embodiments will not further be described.

The principal difference between the orthoses of the two embodiments, is that in this embodiment the rib 71 is provided with proximal 72 and distal 74 pairs of wings that extend from the rib towards the back of the ankle and the plantar aspect of the foot, respectively.

The wings 72, 74 function to increase the lateral stability of the orthosis, and as such the orthosis of this embodiment is particularly well suited for those patients who have weak ankles, as well as problems with resisting plantarflexion. The proximal wings 72 help reduce the chance of the patient rolling over on their ankle by providing a lateral stabilising force to the patient's ankle. The distal wings 74 assist with this function, as well as helping to keep the rib properly aligned with the dorsum of the patient.

The resilience of the wing(s) and rib may be the same or similar, or alternatively, the resilience may be different to account for patients who exhibit - for example - a greater disposition towards rolling over onto their ankle than plantarflexion. It should also be noted that the wings need not be of the same material as the rib.

Figs. 7b and 7c are, respectively, front and side views of the sock illustrating how the rib extends around the ankle and foot to form the aforementioned wings. Figs. 7d and 7e are, respectively rear and underneath plan views of the orthosis.

Fig. 7d shows how the proximal wings 72 extend around either side of the ankle. As shown, a gap 76 is left so that the sock-like structure is still sufficiently elastic in the region of the proximal edge of the orthosis to allow a patient to put on the orthosis.

Fig. 7e shows how the distal wings 74 extend around and partly underneath the foot, again leaving a gap 78 so that the orthosis is sufficiently elastic in the region of the distal edge to allow a patient to put it on.

5 It will be understood from the above that the orthoses of the preferred embodiments provide an effective means to tackle the problem of plantarflexion. Advantageously, and in addition to this function, the orthoses of the invention can significantly augment dorsiflexion during the push-off phase of a patient's gait. The principal reason for this is believed to be that the elastic structure and resilient rib store energy when compressed, and this
10 energy is released during the push-off phase of the patient's gait. It is anticipated, therefore, that patients will not only find that the orthoses of the embodiments tackle the problem of plantarflexion but also actively assist walking process.

15 Whilst various preferred embodiments have been described above in detail, it will be apparent and should be noted that modifications and alterations may be made without departing from the spirit and scope of the invention as defined by the accompanying claims.

For example, the embodiment depicted in Figs. 7a to 7e may be modified to include only a single pair of wings (distal or proximal) or indeed
20 to include further pairs of wings extending from the rib in between , aforementioned the proximal and distal pairs of wings.

CLAIMS

1. An ankle-foot orthosis comprising: an elastic structure formed of contiguous first and second tubular members, said second tubular member being set at an angle to the first tubular member to define, at least in use, a generally L-shaped cavity configured to accept and fit closely about the foot and ankle of a patient; and a rib which is permanently bonded or otherwise permanently affixed to a region of the structure which overlies the dorsum of the patient's foot in use, said rib being formed of a flexible material that has a resilience appropriate for resisting the particular degree of plantarflexion experienced by the patient.
2. An orthosis according to Claim 1, wherein said elastic structure is operable to exert a compressive force on said foot and ankle of said patient.
3. An orthosis according to Claim 2, wherein said elastic structure comprises a compression stocking.
4. An orthosis according to any of Claims 2 to 3, wherein said compressive force is more or less than at least 5 mm Hg (approximately 670 Pascals).
5. An orthosis according to any of Claims 2 to 4, wherein different regions of the elastic structure exert different compressive forces on the foot and ankle of the patient.
6. An orthosis according to Claim 5, wherein said second tubular member exerts a greater compressive force on the foot than the compressive force exerted on the ankle by the first tubular member.
7. An orthosis according to any preceding claim, wherein the rib is of silicone elastomer.

8. An orthosis according to Claim 7, wherein the resilience of the rib, as between a first orthosis and a second orthosis, may be varied by varying the thickness of the rib of one orthosis as compared to the other.

5 9. An orthosis according to Claim 7 or 8, wherein the resilience of the rib, as between a first orthosis and a second orthosis, may be varied by varying the composition of the rib of one orthosis as compared to the other.

10 10. An orthosis according to any of Claims 7 to 9, wherein the rib is of 35 shore silicone elastomer.

11. An orthosis according to any preceding claim, wherein said rib comprises a pair of proximal wings extending from the rib towards the back of the ankle of the patient.

15

12. An orthosis according to Claim 11, wherein said proximal wings extend in parallel to a proximal edge of the elastic structure.

13. An orthosis according to Claim 11 or 12, wherein said proximal wings
20 have the same resilience or a different resilience to that of the rib.

14. An orthosis according to any preceding claim, wherein said rib comprises a pair of distal wings extending from the rib, in the region of the metatarsal heads, towards the plantar aspect of the foot.

25

15. An orthosis according to Claim 14, wherein said distal wings extend generally in parallel to a distal edge of the elastic structure.

16. An orthosis according to Claim 14 or 15, wherein said distal wings
30 have the same resilience or a different resilience to that of the rib.

16. A method of manufacturing an orthosis, the method comprising the steps of: providing an elastic structure formed of contiguous first and second tubular members set at an angle to one another to define, at least in use, a generally L-shaped cavity configured to accept and fit closely about the foot and ankle of a patient; mounting the structure on a foot-shaped anvil; preparing a silicone elastomer having a resilience which is appropriate for resisting the particular degree of plantarflexion experienced by the patient; applying the silicone elastomer to the elastic structure to form a rib that will in use overlie the dorsum of the patient's foot; allowing the silicone elastomer to cure; and removing the elastic structure from the anvil.

17. An orthosis substantially as hereinbefore described with reference to Figs. 6a and 6b of the accompanying drawings.

18. An orthosis substantially as hereinbefore described with reference to Figs. 7a to 7e of the accompanying drawings.

19. A method of manufacturing an orthosis, the method being substantially as hereinbefore described.

ABSTRACTANKLE-FOOT ORTHOSIS

5 An embodiment of the invention provides an ankle-foot orthosis that
comprises: an elastic structure (50) formed of contiguous first (52) and second
(54) tubular members, said second tubular member being set at an angle to the
first tubular member to define, at least in use, a generally L-shaped cavity (56)
configured to accept and fit closely about the foot and ankle of a patient; and a
10 rib (58) which is permanently bonded or otherwise permanently affixed to a
region of the structure which overlies the dorsum of the patient's foot in use,
said rib being formed of a flexible material that has a resilience appropriate
for resisting the particular degree of plantarflexion experienced by the patient.

15 FIG. 6A

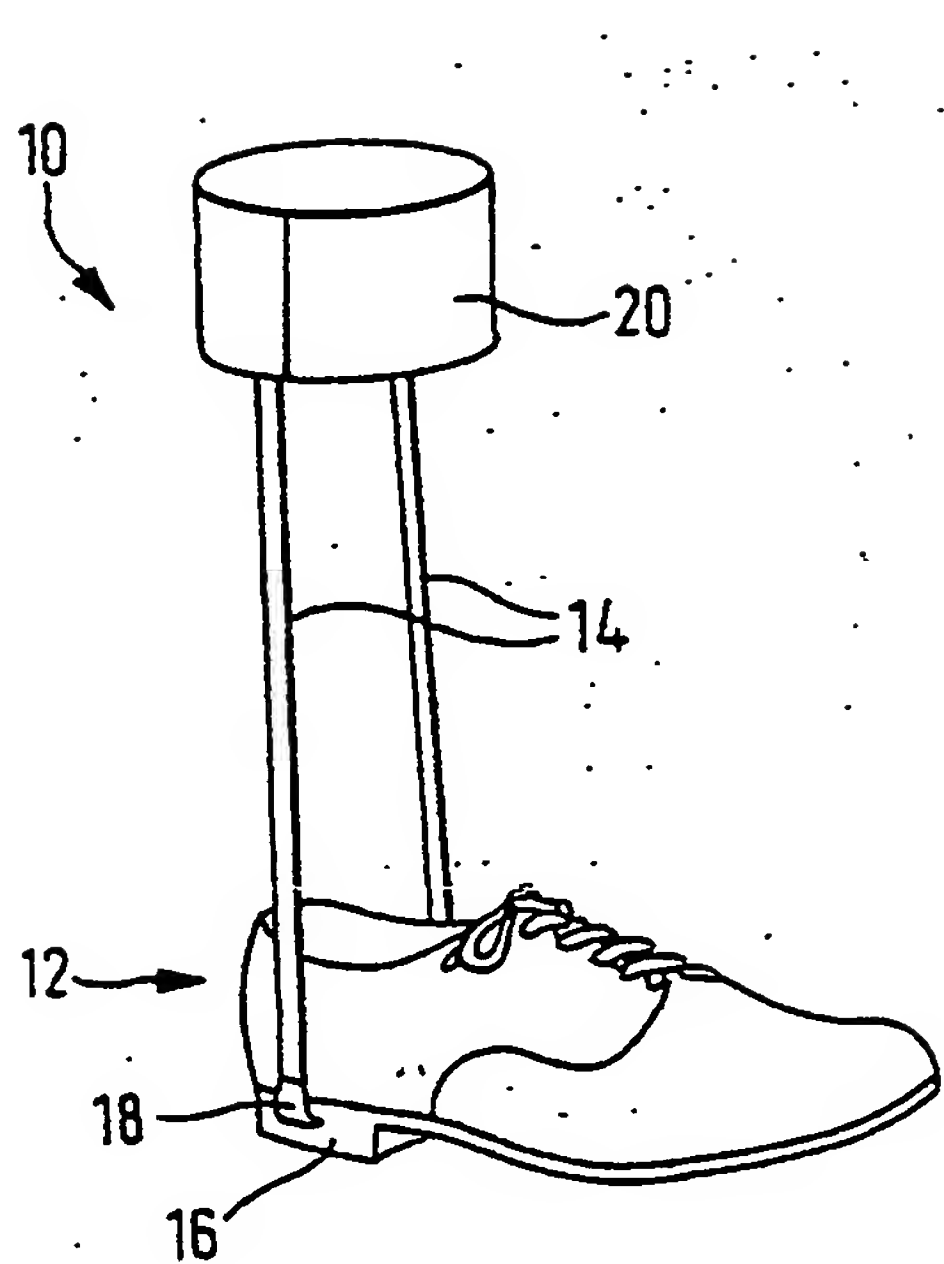


FIG. 1

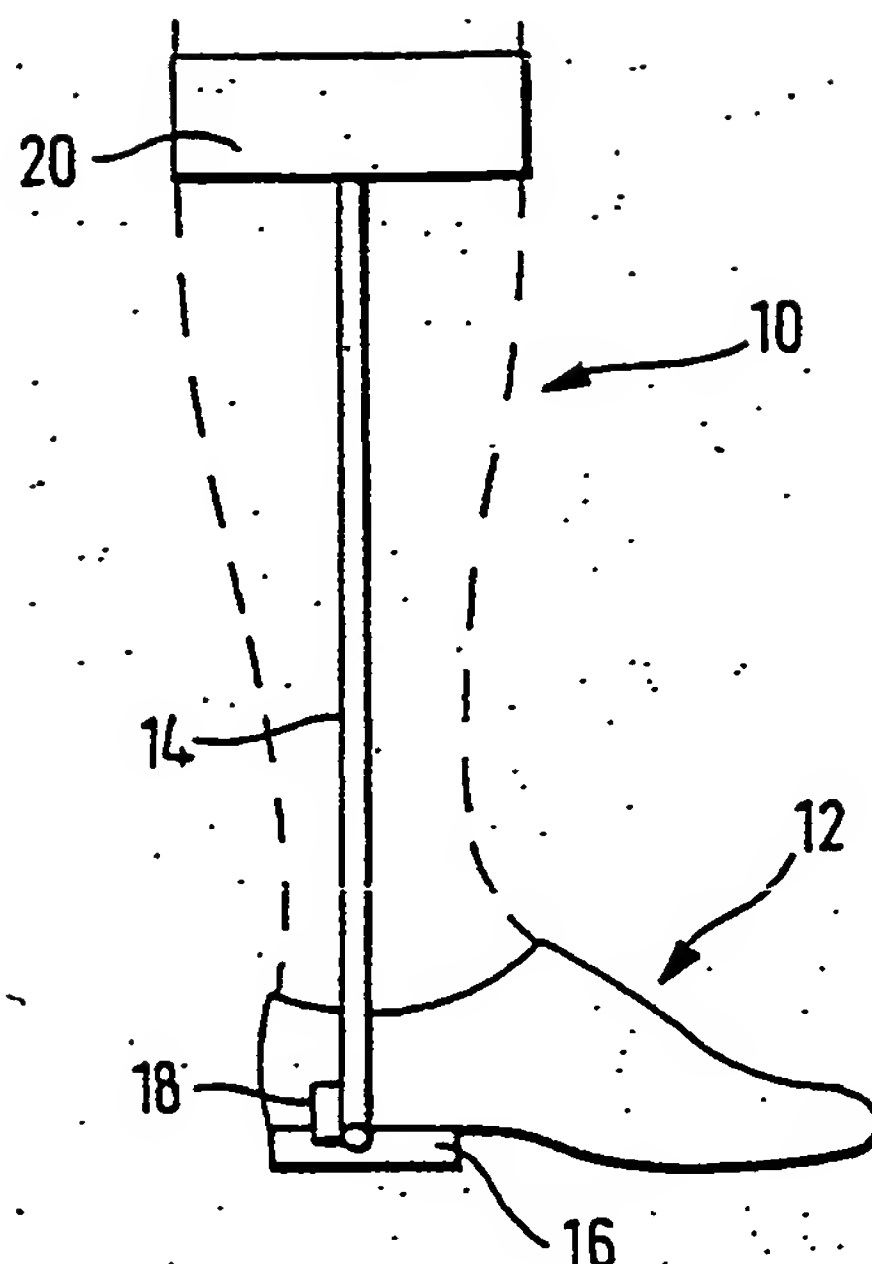


FIG. 2

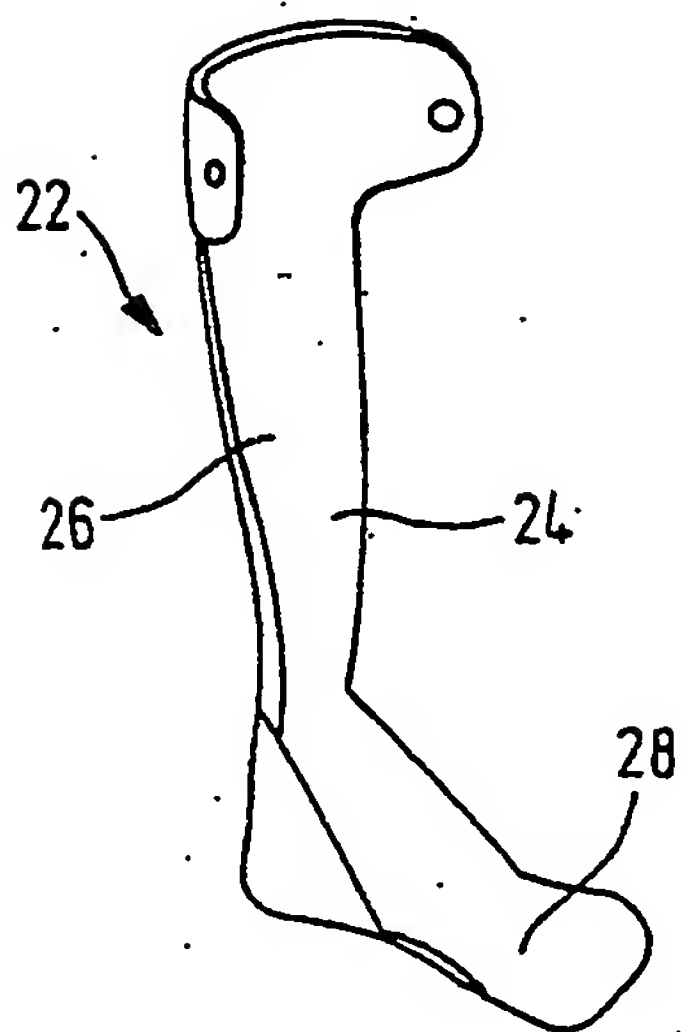


FIG. 3

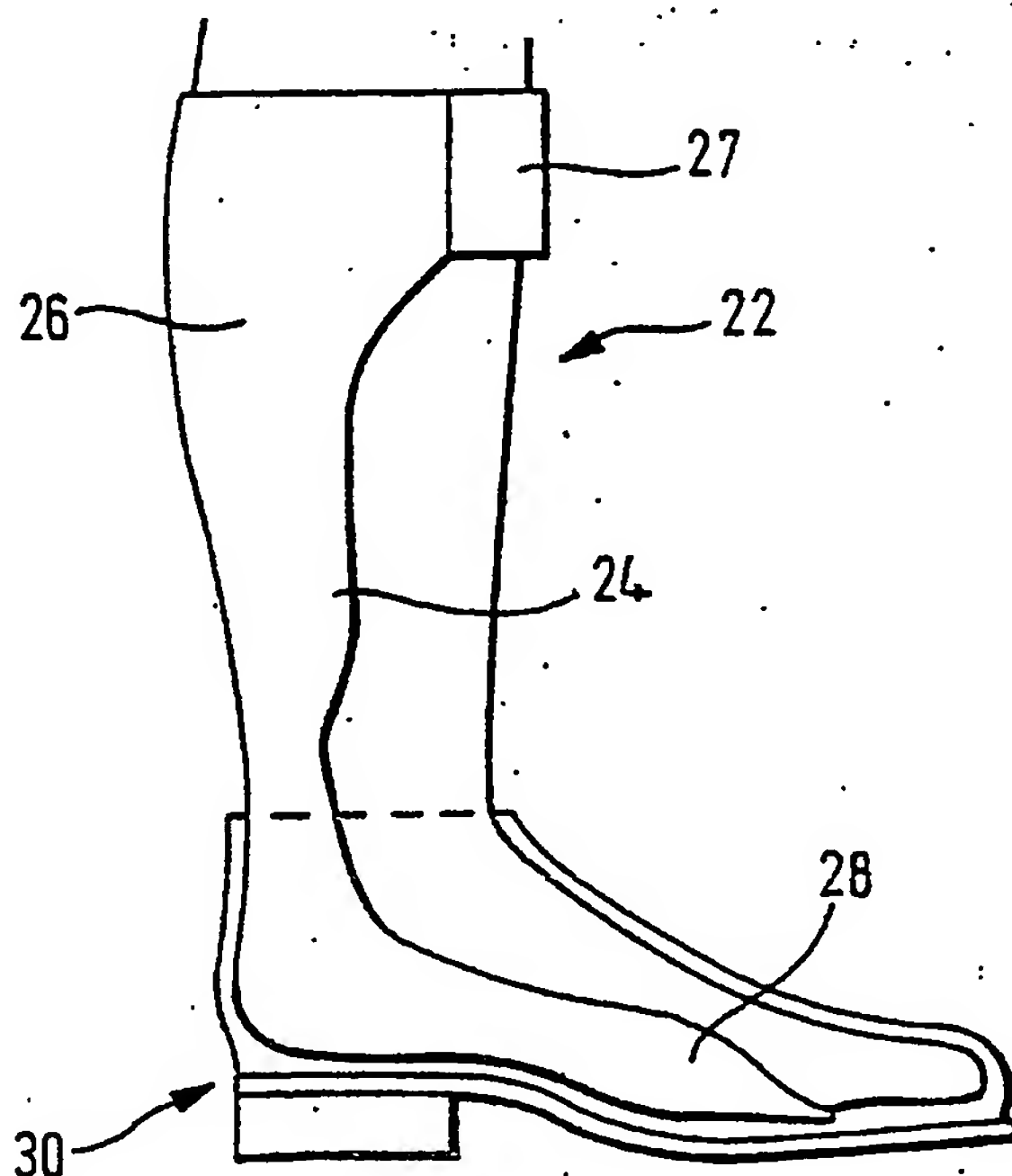


FIG. 4

FIG. 5

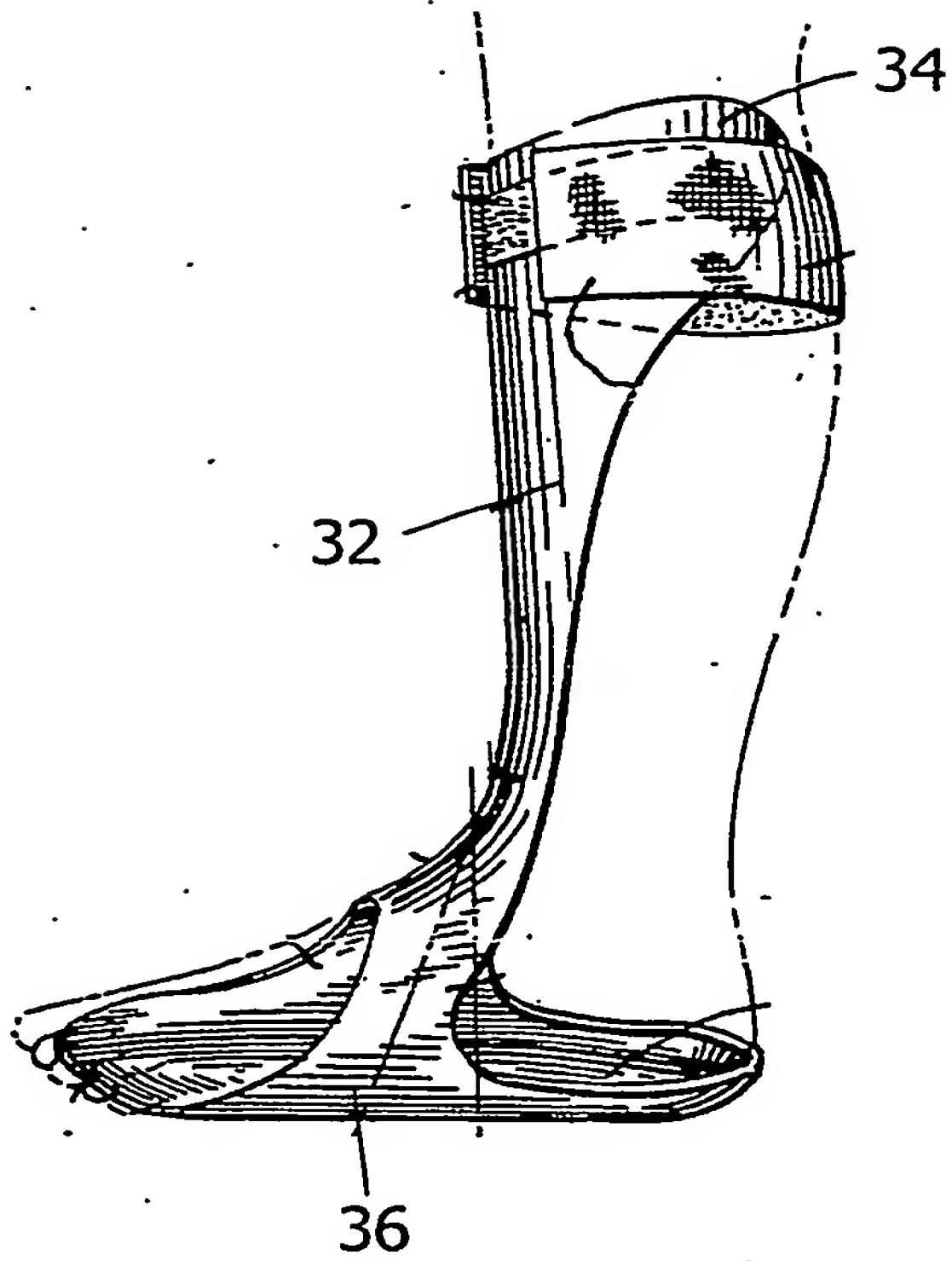
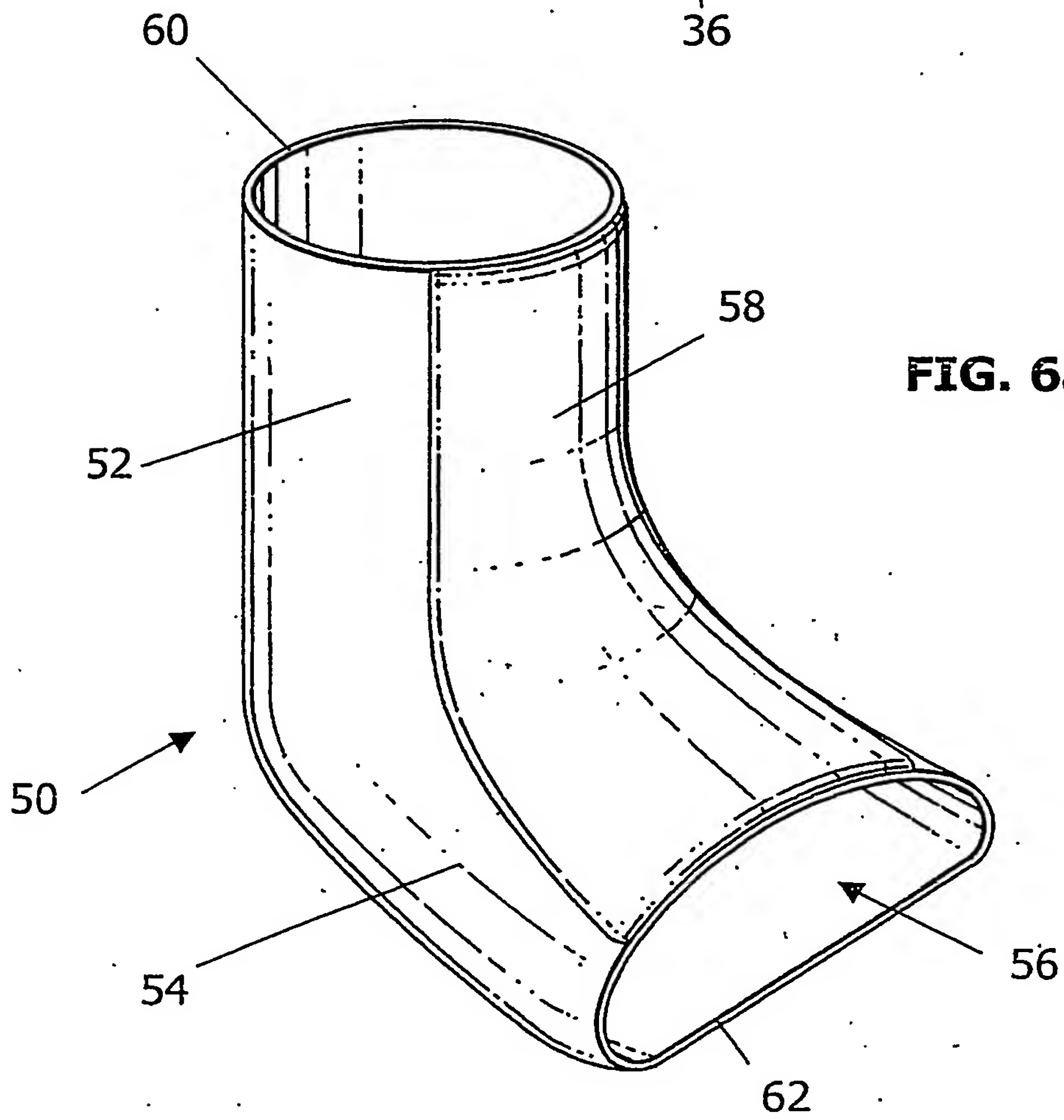


FIG. 6a



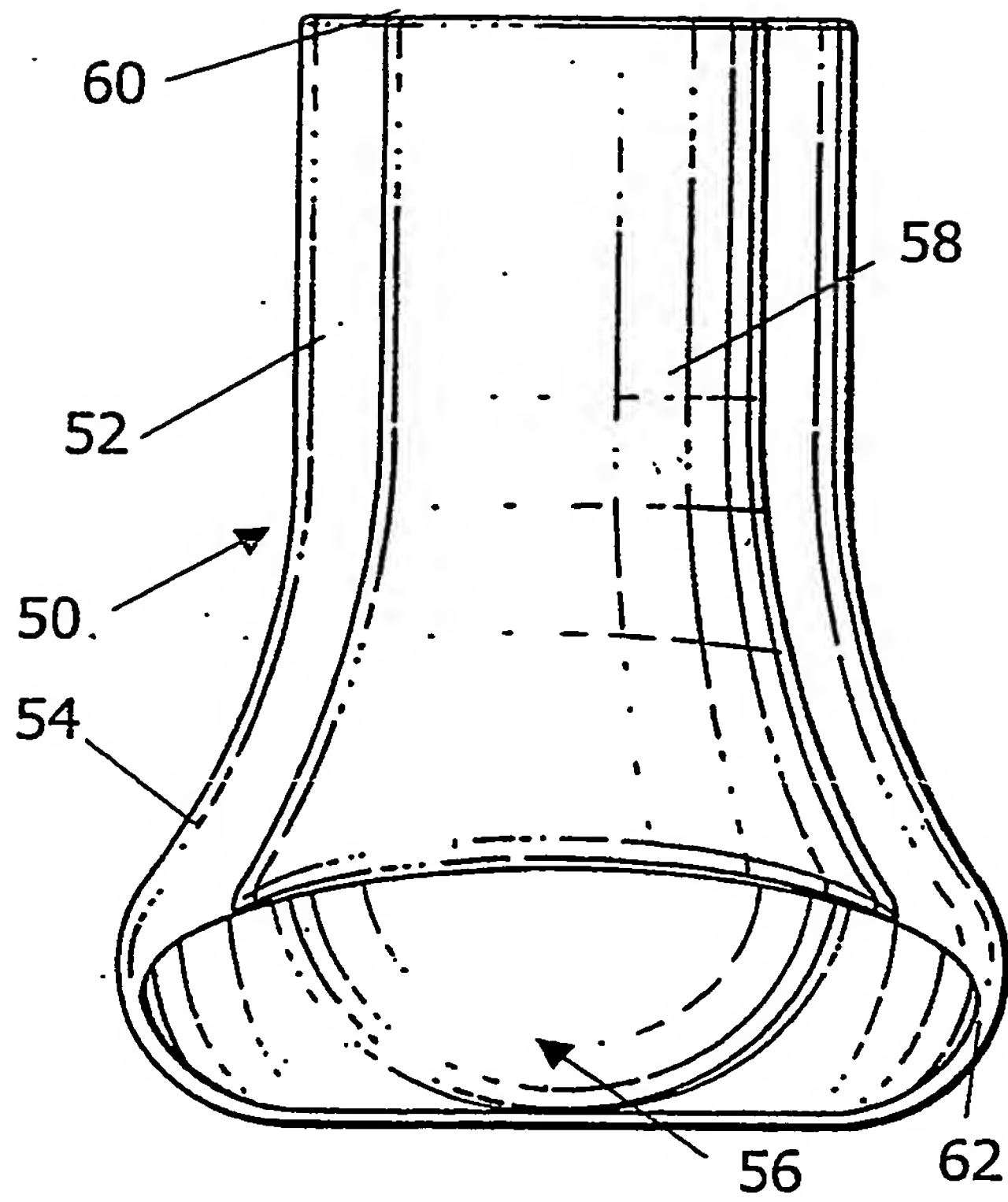


FIG. 6b

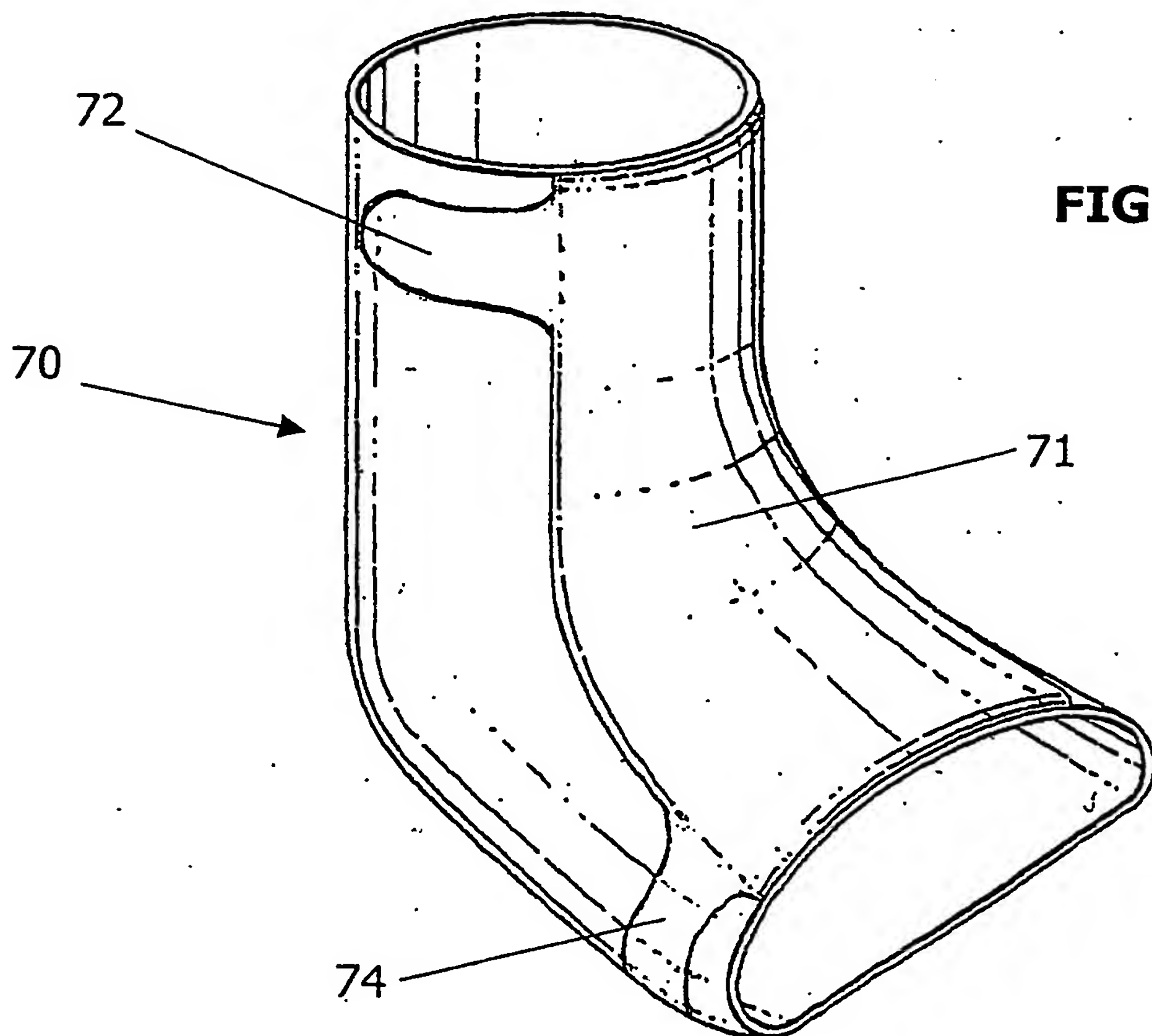
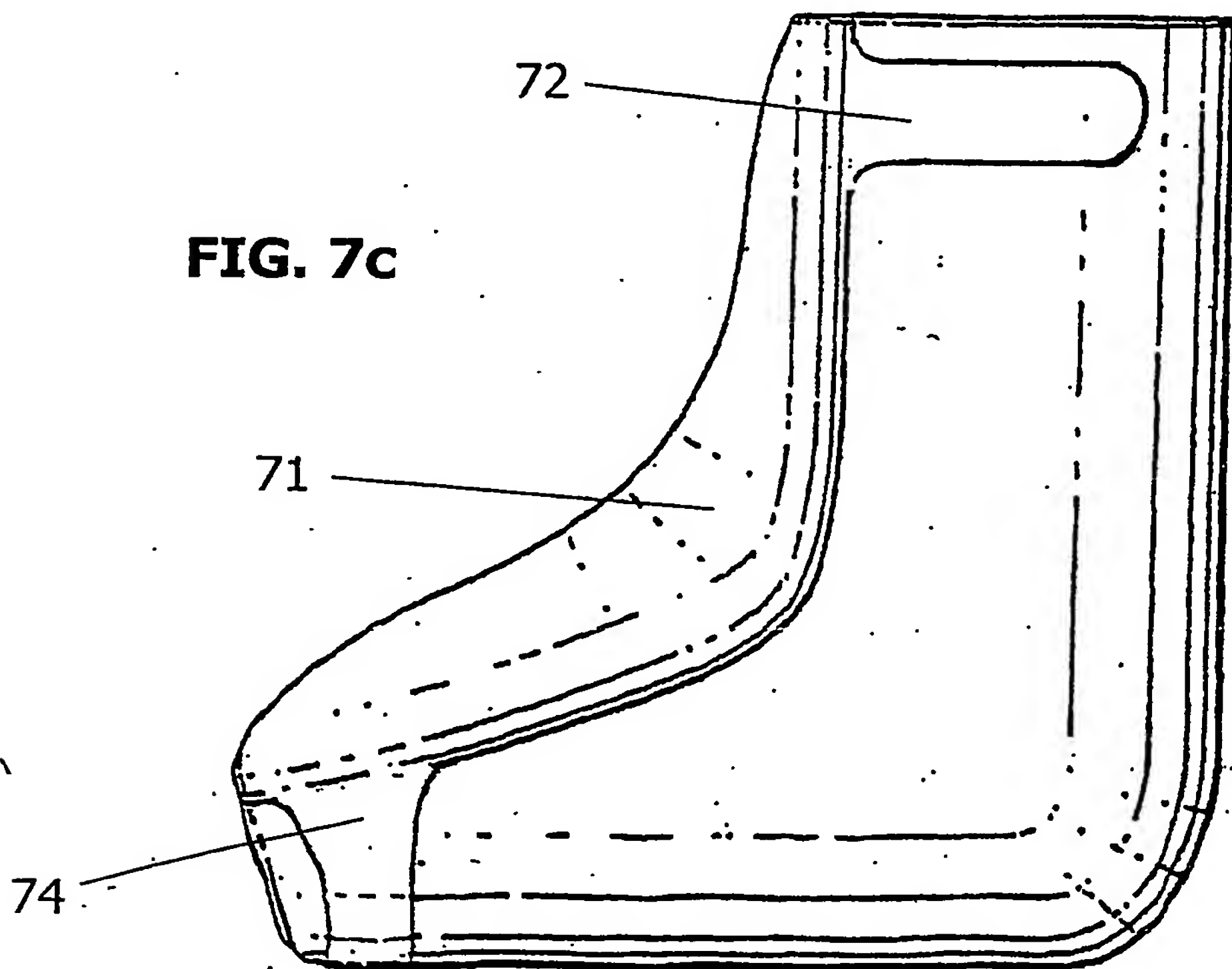
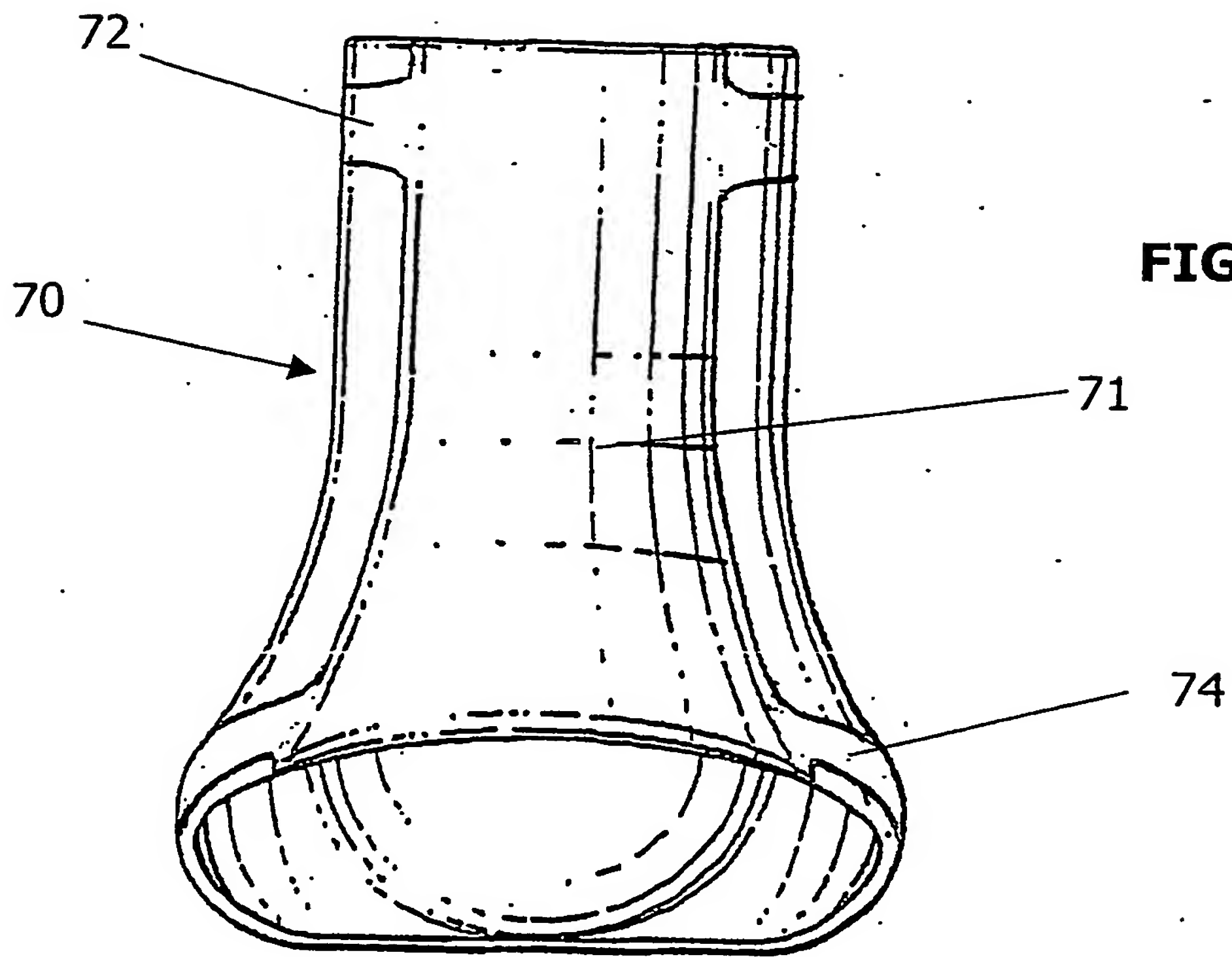


FIG. 7a



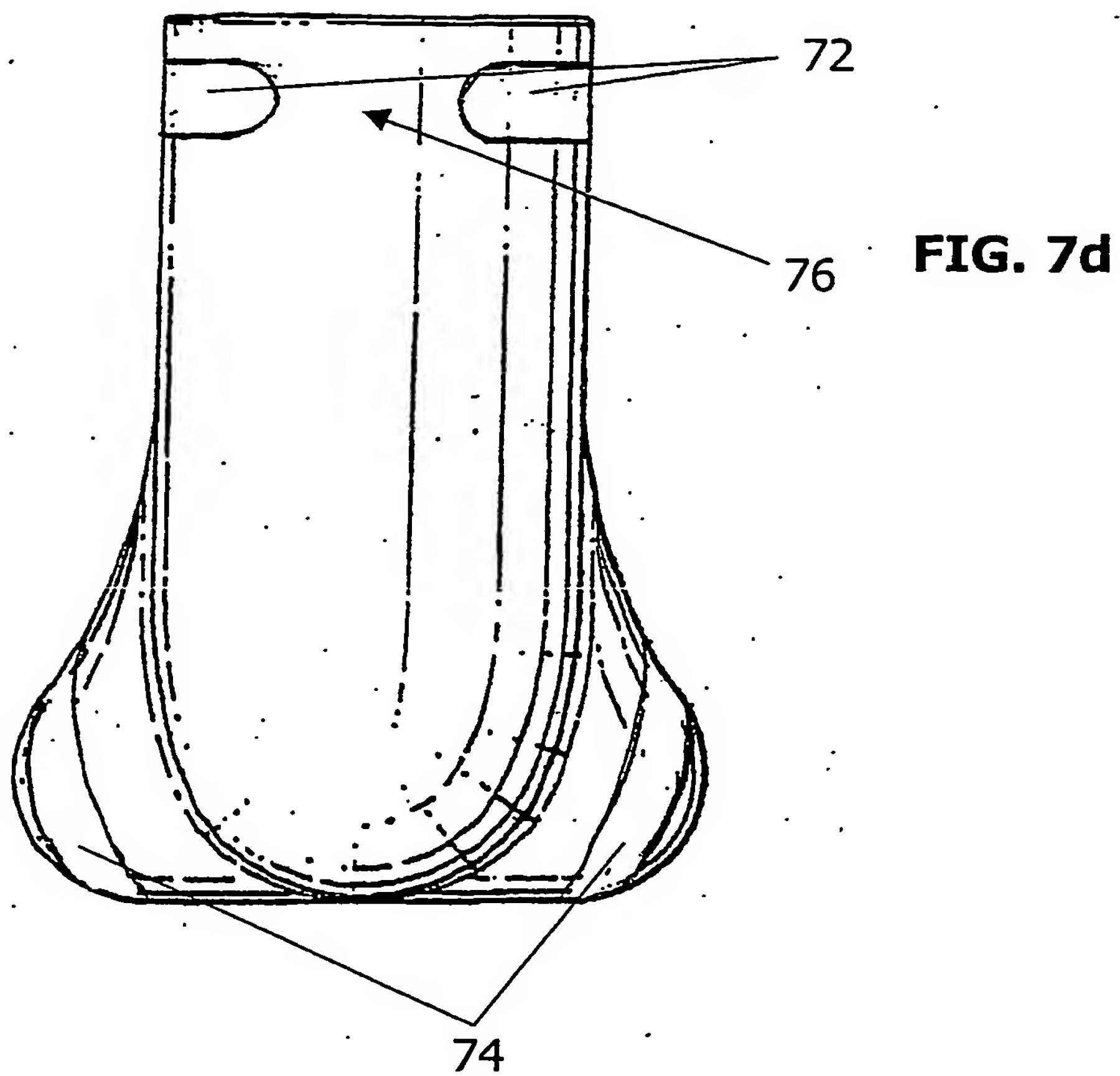
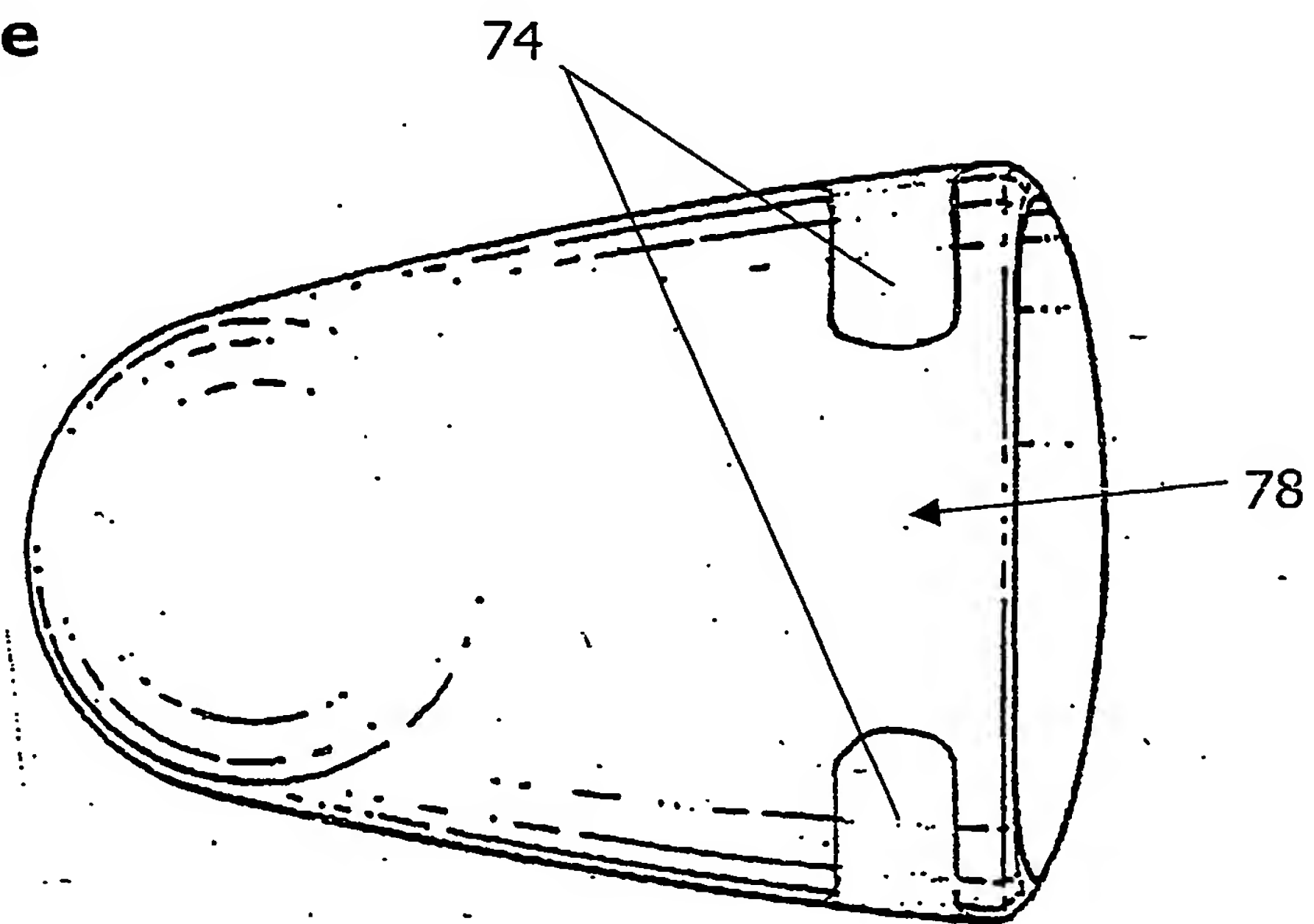


FIG. 7e



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